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|--|-------------|----------------------|------------------------------|------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
| 10/521,325   | 08/15/2005  | Roger Bonnett        | 06275-435US1/100770-1P<br>US | 9186             |
| 26164  | 7590        | 11/14/2008           |                              | EXAMINER         |
| FISH & RICHARDSON P.C.<br>P.O BOX 1022<br>MINNEAPOLIS, MN 55440-1022 |             |                      |                              | YOUNG, SHAWQUIA  |
|  |             |                      | ART UNIT                     | PAPER NUMBER     |
|  |             |                      | 1626                         |                  |
|  |             | NOTIFICATION DATE    | DELIVERY MODE                |                  |
|  |             | 11/14/2008           | ELECTRONIC                   |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

|                              |                                      |                                       |
|------------------------------|--------------------------------------|---------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/521,325 | <b>Applicant(s)</b><br>BONNERT ET AL. |
|                              | <b>Examiner</b><br>SHAWQUIA YOUNG    | <b>Art Unit</b><br>1626               |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 01 August 2008.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1-7, 10, 14 and 15 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-7, 10, 14 and 15 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/96/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-7, 10, 14 and 15 are currently pending in the instant application.

Applicants have added new claim 15 in an amendment filed on August 1, 2008.

#### **I. Response to Arguments/Remarks**

Applicants' amendment, filed on August 1, 2008, has overcome the rejection of claims 1-7, 10 and 14 under 35 USC 112, first paragraph for not being enabled for a solvate of a compound of formula I and the objection of claims 1 and 7 for informalities. The above rejection and objection have been withdrawn.

#### **II. Rejection(s)**

#### **35 USC § 103 - OBVIOUSNESS REJECTION**

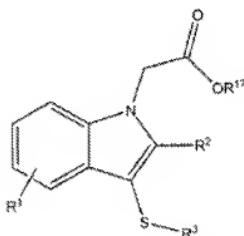
The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*Graham v. John Deere Co.* set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. §103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15 is rejected under 35 U.S.C. § 103(a) as being unpatentable over *Luescher, et al.* (See RN 86704-63-04, CAPLUS). Applicants claim a compound of



formula wherein all of the variables are as defined in  
claim 15.

**The Scope and Content of the Prior Art (MPEP §2141.01)**

*Luescher, et al.* teaches the compound 2-methyl-3-[(2-nitrophenyl)thio]-1H-indole-1-acetic acid.

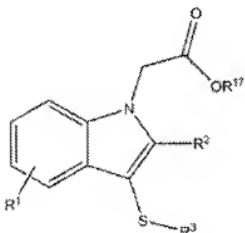
**The Difference Between the Prior Art and the Claims (MPEP §2141.02)**

The difference between the prior art of *Luescher, et al.* and the instant invention is that there both the prior art and the instant compounds are similar in structure but the instant compounds have at least one substituent R<sup>1</sup> attached to the benzene ring of the

indole group. The substituent R<sup>1</sup> includes various groups such as alkyl (i.e. methyl) whereas the prior art teaches that there is no substituent at this position only hydrogen atoms.

**Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)**

Applicants are claiming a compound of the formula



wherein specifically the benzene ring has at least one substituent (i.e. methyl). The prior art reference of *Luescher, et al.* teaches a similar compound wherein the benzene ring is unsubstituted.

In *In re Druey*, 319 F.2d 237, 138 USPQ 39 (CCPA 1963), it was well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. For example, it is obvious to prepare an indole derivative wherein the benzene ring is substituted by an alkyl (i.e. methyl) when the art teaches a similar compound wherein the benzene ring is unsubstituted with a reasonable expectation of success. Specifically, adding a methyl substituent to the benzene ring with the same core structure as taught in the prior art is

obvious absent unexpected results. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare adjacent homologs based on the teachings of the preferred embodiments in the prior art. A strong *prima facie* obviousness has been established.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 10, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the phrase "may be optionally substituted" in the definition of variables R<sup>4</sup> and R<sup>7</sup>-R<sup>15</sup> renders the products indefinite as the phrase "may be optionally substituted" can be considered open-ended language when not clearly defined and therefore is including additional subject matter in the compounds of the formula I or II that is not described in the instant specification and is not particularly pointed out or distinctly claimed. A claim to a chemical compound cannot be open-ended, but must be claimed with precision. This rejection can be overcome by amending the phrase "may be optionally substituted" to read "is (are) optionally substituted" in claims 1-7, 10 and 14.

**III. Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626

/Kamal A Saeed/

Primary Examiner, Art Unit 1626